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Subject: Environmental Defense comments on the Fluoroethane Category

(Submitted via Internet 8/25/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Edwin.L.Mongan-1@usa.dupont.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the **Fluoroethane Category**.

The test plan and robust summaries for the Fluoroethane Category were submitted E.I. du Pont de Nemours and Company. The proposed category is comprised of four members with the following CAS numbers and abbreviations: 76-13-1 (FC113), 354-58-5 (FC 113A), 76-14-2 (FC 114) and 374-07-2 (FC114A). All four members are fully halogenated two-carbon structures containing 2-4 chlorine atoms and at least 3 fluorine atoms.

In general, the test plan and robust summaries are informative and well-written. We agree that the proposed category is reasonable based on structural and toxicological considerations. However, we note that this category designation would be significantly strengthened if data gene array were provided showing that gene expression changes were similar for all proposed members in an appropriate in vitro or in vivo system.

The test plan and robust summaries do not provide information on use, although it is well known that members of this category are used as refrigerants and are associated with the loss of stratospheric ozone because photolysis slowly releases chlorine atoms that are responsible for removing ozone.

The sponsor contends that existing data are sufficient to meet the requirements for all ecotoxicity, environmental fate and physical/chemical characteristics endpoints. We agree but note that these agents are not biodegradable and moderately toxic to fish, aquatic invertebrates and algae.

The sponsor also contends that existing data are adequate for all mammalian toxicity endpoints. We do not agree because there are no existing data on chromosomal aberrations for any of the members, although a dominant lethal test was conducted on FC113. Because some of the in vitro genetic toxicity tests are positive, we recommend that an in vivo test be conducted on at least one other member of the proposed category. Other mammalian toxicity endpoints appear to be covered by a combination of data, discussion and read across approaches. However, we do have two concerns regarding the mammalian toxicity data:

1. The NOEL derived from the repeat dose studies is 2000 ppm and the ACGIH TLV is 1000 ppm (8 hour time-weighted average). This margin of safety does not seem adequate for worker protection. The test plan indicates that concentrations of 5-140 times the TLV caused death, which means that every effort must be made to minimize worker exposure to this class of chemicals and hence the TLV should be lowered.
2. The test plan states that reproductive toxicity studies are not needed because repeat dose studies demonstrate no effect on reproductive organs. However, the robust summaries do not indicate which reproductive organs from the repeat dose studies were examined, although in all cases it is stated that 30-40 different tissues were studied. The robust summaries need to be explicit regarding which reproductive organs and tissues were studied. Also, the section on reproduction on page 11 seems to indicate that effects on reproductive organs were observed in rats for FC 114, since a rat study was conducted and FC 114 is omitted from the list of members with no effects in rats. This should be clarified.

Thank you for this opportunity to comment.

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